

REMARKS

Reconsideration and withdrawal of the rejections of the July 22, 2008 Office Action are respectfully requested in view of the amendments, remarks and enclosures herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 41 and 43-92 are pending, claims 67-81 and 85 are cancelled, and claims 41, 43-66, 82-84 and 86-92 are under examination. Claims 41, 43, 45, 47-50, 54-56, 86, and 88 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claim 56 has been amended to obviate the enablement rejection. Claim 41 has been amended to recite a selection marker and adding a selection agent. Support is found, for example, in ¶¶ 15 and 12 of the specification as published. Claim 49 has been amended to no longer recite “for instance to cold, high salt or minerals”. Claim 50 has been amended to recite from a gene, as per Examiner’s suggestion. Claim 54 has been amended to recite targeting segments. Support can be found, for example, in ¶ 16. Claim 55 has been rewritten to depend from Claim 43. Claims 43, 47-52, 54-56, and 86, 88 have been amended for proper antecedent basis.

No new matter is added.

The Examiner is thanked for withdrawing the previous objections and rejections. It is respectfully submitted that the claims, as originally presented and as amended herein, are patently distinct over the art, and that those claims are and were in full compliance with the requirements of 35 U.S.C. §103. The amendments and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, the amendments and remarks herewith are made simply for clarification and to round out the scope of protection to which Applicant is entitled.

II THE OBJECTIONS TO THE CLAIMS ARE OVERCOME

Claim 43 was objected to because it recites “plastic” rather than “plastid. Claims 54 and 55 were objected to because there was a plurals disagreement. Claims 58-63 were objected to because there was an improper use of an article. Claim 65 was objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of claim 41. Claim 56 was objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of claim 55. The objections are respectfully traversed. The

claims have been amended such that “plastic” has been amended to “plastid”, there is no longer a plurals disagreement, and there is no longer an improper use of an article. Claim 65 has been cancelled. Claim 56 has been amended to further limit the subject matter of claim 41, rather than to further limit the subject matter of claim 55, which obviates the improper dependent form objection of claim 56.

Consequently, reconsideration and withdrawal of the objections is respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME

Claim 56 was rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office Action contends that the vector targeting sequences used for lettuce plastid transformation are too small to function in the claimed method. Claim 56 has been amended to claim the method of claim 41, which obviates the enablement objection to claim 56.

Claims 41, 43, 45-52, 54-66 and 91-92 were rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office Action contends that the specification does not provide enablement for a method of *Asteraceae* transformation where the transformation vector does not comprise a selection marker. Claim 41 has been amended to comprise a vector carrying a selection marker.

Claims 43, 45, 47-52, 54-56, 86 and 88 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to point out and claim the subject matter of the invention.

Claim 50 was rejected because the Office Action contends that is indefinite in its recitation of “wherein the terminator is selected from the group consisting of the *psbA*, *rrn*, *rbcl*, *trnV* and *rps16*” as *psbA*, *rrn*, *rbcl*, *trnV* and *rps16* are entire genes, not just terminators. Claim 50 has been amended to recite “wherein the terminator is selected from a gene from the group consisting of the *psbA*, *rrn*, *rbcl*, *trnV* and *rps16*”.

Claim 43 was rejected for allegedly lacking antecedent basis for the limitations “the expression vector”, “the transforming DNA of interest” and “the plastid genome of interest”. Claim 43 has been amended to recite “a expression vector”, “a transforming DNA of interest” and “a plastid genome of interest”.

Claim 45 was rejected because the Office Action contends that it is indefinite in its recitation of “their genome”. Claim 45 has been amended to recite “the transformants’ genome”.

Claim 47 was rejected for allegedly lacking antecedent basis for the limitation “the promoter”. Claim 47 has been amended to recite “a promoter”.

Claims 48-49 were rejected for allegedly lacking antecedent basis for the limitation “the DNA of interest”. Claims 48-49 were amended to recite “a DNA of interest”.

Claim 49 was rejected because the Office Action contends that it is indefinite for reciting a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation. The limitation of “cold, high salt or minerals” of Claim 49 has been removed, which obviated the indefinite objection to claim 49.

Claim 50 was rejected for allegedly lacking antecedent basis for the limitation “the terminator”. Claim 50 has been amended to recite “a terminator”.

Claims 51-52 were rejected for allegedly lacking antecedent basis for the limitation “the selection marker”. An amendment to claim 41 to include “a vector carrying a DNA sequence of interest and a selection marker” obviates the lack of antecedent basis objection to claims 51-52.

Claims 54 and 55 were rejected for allegedly lacking antecedent basis for the limitations “the DNA segments” and “the plastid genome of interest”. Claims 54 and 55 have been amended to recite “DNA targeting segments” and “the plastid genome of interest” has been removed.

Claims 55 and 56 were rejected for allegedly lacking antecedent basis for the limitation “the set of DNA segments”. Claims 55 and 56 have been amended to recite “a set of DNA segments”.

Claim 86 was rejected for allegedly lacking antecedent basis for the limitation “the gene of interest”. Claim 86 has been amended to recite “a gene of interest”.

Claim 88 was rejected for allegedly lacking antecedent basis for the limitation “Plant parts as claimed in 82” as the Office Action contends that claim 82 only claims part of a plant. Claim 88 has been amended to recite “A plant part as claimed in 82”.

Accordingly, reconsideration and withdrawal of the Section 112 claim rejection is respectfully requested.

III THE ART REJECTIONS UNDER U.S.C. 35 § 103 ARE OVERCOME

Claims 41, 43-47, 51, 54, 57-60, 64-66, 82-83, 86-89 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Koop *et al.* (1996, Planta 199:193-201). The Office Action contends that it would have been obvious to one of ordinary skill in the art to modify the method of plastid transformation as taught by Koop *et al.* to apply the method to other plant

species, including *Asteraceae* like lettuce. The Office Action also contends that it would have been obvious to replace the tobacco flanking regions in the vector with the corresponding ones from the *Asteraceae* plastid one wished to transform, including that of lettuce. Claims 49-50, 55-56 and 61-63 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Koop *et al.* (1996, *Planta* 199:193-201) as applied to claims 41, 43-47, 51, 54, 57-60, 64-66, 82-83, 86-89 above, and further in view of Blowers *et al.* (WO 99/05265). The Office Action contends that it would have been obvious to modify the method of lettuce plastid transformation taught by Koop *et al.*, to use the psbA terminator, use of lettuce 70B/trnV/16S/trnI/trnA as flanking sequences, and particle bombardment as the transformation method as described by Blowers *et al.* Claims 48 and 49 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Koop *et al.* (1996, *Planta* 199:193-201) as applied to claims 41, 43-47, 51, 54, 57-60, 64-66, 82-83, 86-89, and further in view of Daniell *et al.* The Office Action contends that it would have been obvious to modify the method of transforming *Asteraceae* as taught by Koop *et al.* to express a DNA encoding a therapeutic or prophylactic (bio)pharmaceutical (poly)peptide as described in Daniell *et al.* The rejections are respectfully traversed.

Applicants respectfully point out that in Koop *et al.* it is said in the very last sentence that “the applicability of each [transformation] method for different species will have to be determined in the future”. Koop *et al.* clearly recognized that different species require different protocols. Thus, it is not obvious to modify for lettuce the tobacco method of Koop *et al.*

Moreover, there are some crucial differences between the method of plastid transformation of Koop *et al.* and the Applicant’s method. The Applicant’s method requires selection in a relatively early stage (page 4, lines 25-29 refer to a preferred maximum of 2-5 days and in the PEG protocol of Example 6 selection is after 6 days) and the Applicant’s method does not use “fresh” culture medium for the initial selection, rather the selection agent is added to the medium in which the plastid suspension is cultured, and the medium is refreshed after some weeks. By contrast, after two weeks Koop *et al.* transfer the bacterial colonies to fresh culture medium that includes the selection agent (see page 195, left hand column halfway under “Protoplast embedding, culture and plant regeneration” and under “Selection”).

Claim 41 has been amended to more clearly reflect the differences between the Applicant’s method and the method, which obviates the unpatentable objection to claim 41 and the claims depend from 41.

Applicants also respectfully point out that the Office action acknowledges that Blowers *et al.* teach transformation of tobacco plastid genomes. Tobacco is a *Solanaceae* plant, not an *Asteraceae* plant. Blower *et al.* do not teach subjecting a plant material derived from *Asteraceae*, which comprises plastids, to a transformation treatment.

Additionally, there are some crucial differences between the method of plastid transformation of Blowers *et al.* and the Applicant's method. Blower *et al.* teach a method using a solid medium. On page 42, Blowers *et al.* teach placing tobacco NT1 suspension onto solid NT1 medium containing either 0.4 M mannitol or a combination of 0.2M sorbitol/0.2M mannitol. Claim 41 and claims 43-47, 51, 54, 57-60, 64-66, 82-83, 86-89 that depend from claim 41, all recite the medium is liquid. These failures are not overcome by Daniell *et al.*

Therefore, the combination of Koop *et al.* and Blowers *et al.* with Daniell *et al.* do not make obvious the invention as recited in claims 41, 43-51, 54-66, 82-83, 86-89. Accordingly, Applicants respectfully request that these rejections be withdrawn.

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the rejections of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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